

Application Evaluation

In all instances Sartorius Stedim Biotech works in close partnership with the client, so as to understand how to effectively implement and achieve the maximum benefit of Sartorius Stedim Biotech Systems. This approach will quickly identify those applications where bags are not suitable.

New Installations - Single-use disposables bring noticeable benefits in the case of a new facility. As a single-use disposable, closed system, the technology opens up new opportunities for facility design. Layout and storage can be designed around bag technology, maximising operational efficiency and capital.

Existing Installations - The application is more complex but the benefits can be large, especially where there are constraints to production that play to the single-use disposables advantage, specifically:

- Shortage of critical utilities
- Floor area constraints
- Not enough CIP capacity in downstream processing
- Problems with containment of the product based on existing equipment

Scale - There is a practical limit to the size of a bag that can be moved around by operators without mechanical assistance. This is often taken as 1000L. Processes requiring bags larger than 1000L will need either multiple 500L bags (which can be mobile) or 1500L to 2500L bags (positioning of the bags in relation to process equipment must be carefully considered).

Considering Palletank®, Rack and Drum Position

Process - A number of process related factors must be accounted for when determining the applicability of single-use disposables:

- Sartorius Stedim Biotech Bag Process Compatibility
- Physical Operations
- Process Operations

Type - Facilities can be dedicated to a single product or designed for the manufacture of multiple products. Multi-product facilities favour single-use disposables since they are inherently associated with product changeovers. Each product changeover requires rigorous stripping down and cleaning of equipment and processing areas in order to avoid cross contamination. The application of single-use disposables significantly simplifies both the cleaning requirements and the potential for cross contamination.

